

Remarks/Arguments

Claims 1-4, 8-9, 12, 20, 43-55 and 59-64 have been amended. Accordingly, Claims 1-64 are currently pending.

I. Amendments:

Amended Claim 1 now recites that the hyaluronic acid (HA) isolate includes an eggshell membrane fraction rich in HA naturally occurring in an eggshell membrane source. Support for amended Claim 1 can be found through out the specification and, more specifically, at page 7, paragraph 0028. Accordingly, no new matter has been added to amended Claim 1.

Claims 2-4, 8-9 and 12 have been amended to be consistent with amended Claim 1. As such, no new matter has been added.

Claim 20 has been amended to clarify that the HA composition is produced by extracting an HA rich fraction from eggshell membrane. Support for amended Claim 20 can be found throughout the specification and, more specifically, at page 7, paragraph 0028. As such, no new matter has been added.

Claim 43 has been amended to clarify that the composition includes an eggshell membrane fraction rich in HA naturally occurring in an eggshell membrane source. Support for amended Claim 43 can be found throughout the specification and, more specifically, at page 16, paragraph 0068. Again, no new matter has been added.

Claims 44-50 have been amended to be consistent with amended Claim 43. As such, no new matter has been added.

Claim 51 has been amended to clarify that the composition can be a lubricant for use in cosmetics or eye drops or a moisturizing agent for use in cosmetics or eye drops. Support

for amended Claim 51 can be found at page 16, paragraph 0067. No new matter has been added.

Claim 52 has been amended in similar fashion to Claim 43 and Claims 53-55 have been amended to be consistent with amended Claim 52. Again, no new matter has been added.

Claim 59 has been amended to correct a typographical error and to clarify that it is directed to a method, and Claim 60 has been amended for the same reason and to be consistent with amended Claim 51. As such, no new matter has been added.

Claim 61 has been amended to clarify that the method includes the step of extracting an HA rich fraction from eggshell membrane. Support for amended Claim 61 can be found throughout the specification and, more specifically at page 16, paragraph 0068. No new matter has been added.

Claims 62 and 63 have been amended to be consistent with amended Claim 61 and Claim 64 has been amended to be consistent with amended Claim 51. Again, no new matter has been added.

II. The Invention:

The invention is directed to a unique composition isolated from eggshell membrane that is rich in hyaluronic acid (HA) naturally occurring in the eggshell membrane. The composition can be in a purified form, i.e. a form in which the concentration of the naturally occurring HA has been increased. This HA containing composition is clearly different than HA compositions derived from sources other than eggshell membrane, e.g., compositions derived from animal tissue or bacteria.

The invention is also directed to methods for producing the composition and methods of treating a mammal by administering such a composition to the mammal.

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The cited prior art references do not disclose compositions isolated from eggshell membrane rich in HA naturally occurring in the eggshell membrane, as claimed.

III. Rejections:

Rejections based on 35 U.S.C. §112, second paragraph

On pages 2-3 of the Office Action, Examiner Krishnan rejected Claims 25-28, 47-50, 59, 60 and 64 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner contends that claims 25 through 28 are indefinite because they each refer to a hyaluronic acid composition and claim 20, from which they depend, recites two hyaluronic acid compositions. As claim 20 has been amended to only recite one HA composition, it is respectfully submitted that the rejection is now moot and should be withdrawn.

The Examiner also contends that claim 43 is indefinite because it recites an HA component and it is unclear what it is referring to. As claim 43 has been amended to clarify that the composition comprises an eggshell membrane fraction rich in HA, it is respectfully submitted that the rejection is now moot and should be withdrawn.

Similarly, the Examiner contends that claims 47 through 50 are unclear because they each recite an HA component comprising HA. As each of these claims have been amended to delete the recitation of an HA component, it is respectfully submitted that the rejection is now moot and should be withdrawn.

The Examiner also contends that claims 51, 60 and 64 are not clear as to what "a lubricant or moisturizing agent in cosmetic or eye drops" means. As these claims have been amended to clarify the quoted language, it is respectfully submitted that the rejection is now moot and should be withdrawn.

Finally, the Examiner contends that there is insufficient antecedent basis in claims 59 and 60 for the limitation "composition." As claims 59 and 60 have been amended to recite that they depend from the "method" of claim 52, it is respectfully submitted that the rejection is now moot and should be withdrawn.

Accordingly, it is respectfully requested that the rejections under 35 U.S.C. §112, second paragraph, be withdrawn.

Rejections based on Balazs

On pages 3-4 of the Office Action, Examiner Krishnan rejected Claims 1-11, 43-46, 61 and 62 under 35 U.S.C. §102(b) as being anticipated by Balazs (US 4,141,973).

Balazs is directed to an ultrapure hyaluronic acid (HA) and a method for producing same. Balazs teaches that the HA is obtained by extracting it from animal tissue, i.e., connective tissue such as rooster combs and human umbilical cords. See column 3, lines 22-28 and the examples at pages 10-11. Balazs further teaches that in order to provide a high concentration of HA which would avoid an inflammatory reaction when administered to an animal, extensive purification steps must be conducted. See examples at pages 10-15.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir. 1989).

Nowhere does Balazs disclose an HA isolate that includes an eggshell membrane fraction rich in HA naturally occurring in eggshell membrane. This eggshell membrane material is clearly different from the HA compositions disclosed by Balazs.

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In fact, Balazs actually teaches away from a composition containing an eggshell membrane fraction that includes HA naturally occurring in eggshell membrane, by teaching that the HA material is naturally found in animal tissue and is extracted from such tissue.

Therefore, as Balazs does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Balazs cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 1-11, 43-46, 61 and 62 under 35 U.S.C. §102(b), in view of Balazs, be withdrawn.

Rejections based on Henderson et al.

On page 4 of the Office Action, Examiner Krishnan rejected Claims 12-16, 50, 51, 59 and 60 under 35 U.S.C. §102(b) as being anticipated by Henderson et al. (US6,255,295).

Henderson et al. is directed to a composition for the protection, treatment and repair and for reducing inflammation of connective tissue in mammals by administering the composition to the mammal. The composition includes a combination of at least two compounds that can include hyaluronic acid (HA) and glucosamine. However, nowhere do Henderson et al. disclose a composition that includes an eggshell membrane fraction rich in HA naturally occurring in the eggshell membrane, let alone a combination of both HA and a hexosamine which are naturally occurring in the eggshell membrane.

Therefore, as Henderson et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Henderson et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 12-16, 50, 51, 59 and 60 under 35 U.S.C. §102(b), in view of Henderson et al., be withdrawn.

Rejections based on Osuoji

On pages 4-5 of the Office Action, Examiner Krishnan rejected Claims 20-28 and 35-39 under 35 U.S.C. §102(b) as being anticipated by Osuoji (*Biochimica et Biophysica Acta*, 1971, 244, 481-483).

Osuoji is directed to the study of the acid glycosaminoglycan content of the membranes of shell free eggs taken from the oviduct of hens. Osuoji detected very low levels (i.e., less than 0.1 wt %) of HA in the membrane of the shell free eggs and failed to detect any other acid glycosaminoglycans in the membrane, such as chondroitin sulfate. The chondroitin sulfate was only found in the hen oviduct tissue itself and not in the membrane of the shell free eggs.

The shell free eggs studied by Osuoji are immature eggs that have not yet formed an eggshell. As such, they are clearly different from eggshell membrane (from mature eggs having an eggshell) as claimed. The fact that the membranes of the shell free eggs studied by Osuoji contained no chondroitin sulfate clearly shows that they are different from the eggshell membranes as claimed. Nowhere does Osuoji disclose a method that includes extracting an HA rich fraction from eggshell membrane. Moreover, nowhere does Osuoji disclose any other material naturally found in eggshell membrane.

Therefore, as Osuoji does not disclose each and every element as set forth in the present claims and does not show the identical invention in as complete detail as claimed, it is respectfully submitted that Osuoji cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 20-28 and 35-39 under 35 U.S.C. §102(b), in view of Osuoji, be withdrawn.

Rejections based on Bracke

On page 5 of the Office Action, Examiner Krishnan rejected Claims 29-31 under 35 U.S.C. §102(b) as being anticipated by Bracke et al. (US 4,517,295).

Bracke et al. is directed to HA prepared in high yield from streptococcus bacteria by fermenting the bacteria. Nowhere does Bracke et al. disclose a method which includes extracting an HA rich fraction from eggshell membrane.

In fact, Bracke et al. actually teach away from extracting an HA rich fraction from eggshell membrane, by teaching that the HA material is derived from bacteria.

Therefore, as Bracke et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Bracke et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 29-31 under 35 U.S.C. §102(b), in view of Bracke, et al., be withdrawn.

Rejections based on Sakurai

On page 5 of the Office Action, Examiner Krishnan rejected Claims 32-34 under 35 U.S.C. §102(b) as being anticipated by Sakurai et al. (US 4,716,224).

Sakurai et al. is directed to a crosslinked HA prepared by crosslinking the HA or HA salt with a polyfunctional epoxy compound. Nowhere does Sakurai et al. disclose a method which includes extracting an HA rich fraction from eggshell membrane.

In fact, Sakurai et al. actually teach away from extracting an HA rich fraction from eggshell membrane, by teaching that the HA material is derived from known animal tissues, such as umbilical cord, rooster comb, and vitreous body.

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Therefore, as Sakurai et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Sakurai et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 32-34 under 35 U.S.C. §102(b), in view of Sakurai et al., be withdrawn.

Additional Rejections based on Henderson et al.

On pages 5-6 of the Office Action, Examiner Krishnan rejected Claims 52-58 under 35 U.S.C. §102(b) as being anticipated by Henderson et al. (US 6,255,295).

For the same reasons discussed more fully above, it is respectfully submitted that nowhere do Henderson et al. disclose a method that includes administering a composition which includes an eggshell membrane fraction rich in HA naturally occurring in the eggshell membrane.

Therefore, as Henderson et al. do not disclose each and every element as set forth in the present claims and do not show the identical invention in as complete detail as claimed, it is respectfully submitted that Henderson et al. cannot anticipate the present claims. See *Verdegaal*, 814 F.2d at 631 and *Richardson*, 868 F.2d at 1236.

Accordingly, it is respectfully requested that the rejections of Claims 52-58 under 35 U.S.C. §102(b), in view of Henderson et al., be withdrawn.

Rejections based on 35 U.S.C. §103

35 U.S.C. §103 Rejections based on Henderson

On page 7 of the Office Action, Examiner Krishnan rejected Claims 17-19 and 47-49 under 35 U.S.C. §103(a) as being obvious over Henderson (US 6,255,295).

As discussed above, Henderson et al. is directed to a composition for the protection, treatment and repair and for reducing inflammation of connective tissue in mammals by administering the composition to the mammal. Although Henderson et al. disclose that the composition can include HA, they do not disclose a composition that includes both HA and chondroitin sulfate, as required by claims 17-19. Moreover, it is clear that Henderson et al. fail to disclose a composition that includes an eggshell membrane fraction rich in HA naturally occurring in the eggshell membrane, let alone a combination of both HA and chondroitin sulfate which are naturally occurring in the eggshell membrane.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. See MPEP § 2142.

The teaching or suggestion to make the claimed combination (or modification) and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, the reference must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Thus, unless there is some suggestion or motivation contained within the reference to modify its teachings to include an HA isolate containing an eggshell membrane fraction rich in HA naturally occurring in the eggshell membrane (claims 47-49) or both the membrane fraction and chondroitin sulfate naturally occurring in the eggshell membrane (claims 17-19) having all the claim limitations, a *prima facie* case of obviousness cannot be established.

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It is respectfully submitted that there is no suggestion or motivation in the Henderson et al. reference to modify its teachings to provide such compositions.

Accordingly, it is respectfully requested that the rejections of Claims 17-19 and 47-49 under 35 U.S.C. §103(a), in view of Henderson et al., be withdrawn.

Rejections based on Osuoji in combination with Baker

On page 8 of the Office Action, Examiner Krishnan rejected Claims 40-42 under 35 U.S.C. §103(a) as being obvious over Osuoji, in combination with Baker et al. (Biochemical Journal, 1962, 82, 352-361).

As discussed above, Osuoji does not disclose extracting HA from eggshell membrane, as claimed. Instead, Osuoji merely identified very small quantities of HA in the membrane of shell free eggs.

Baker et al. is directed to the study of the organic material of hen's egg shell. Baker et al. reported that the eggshell itself contains chondroitin sulfate. Nowhere do Baker et al. disclose, teach or suggest a composition containing chondroitin sulfate naturally occurring in eggshell membrane.

Accordingly, as neither Osuoji nor Baker et al. taken alone or combined teach or suggest all of the claim limitations of claims 40-42, a *prima facie* case of obviousness cannot be established.

Therefore, it is respectfully requested that the rejections of Claims 40-42 under 35 U.S.C. §103(a), in view of Osuoji in combination with Baker et al., be withdrawn.

Rejections based on Balazs in combination with Henderson

On page 9 of the Office Action, Examiner Krishnan rejected Claims 61, 63 and 64 under 35 U.S.C. §103(a) as being unpatentable over Balazs (US 4,141,973) in combination with Henderson et al. (US 6,255,295).

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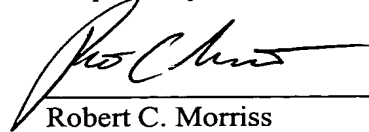
- As discussed more fully above, neither Balazs nor Henderson et al. teach or suggest a method which includes extracting an HA rich fraction from eggshell membrane (claim 61) or an HA rich fraction that also includes at least one other naturally occurring constituent of the eggshell membrane (as specified in claim 63). Accordingly, neither Balazs nor Henderson et al. taken alone or combined teach or suggest all of the claim limitations of claims 61, 63 and 64. Moreover, Balazs actually teaches away by teaching that the HA composition is extracted from animal tissue.

Therefore, it is respectfully requested that the rejections of Claims 61, 63 and 64 under 35 U.S.C. §103(a), in view of Balazs in combination with Henderson et al., be withdrawn.

CONCLUSION

Applicants respectfully submit that the application as amended, including claims 1-64, is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to examination of the application, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,



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